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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Center	<i>[Signature]</i>

International Conference on Harmonisation Workshop on Oncolytic Viruses;  
Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop entitled "ICH Workshop on Oncolytic Viruses." The workshop will be held in conjunction with the International Conference on Harmonisation (ICH) expert working group and steering committee meetings in Chicago, IL. The objective of the workshop is to identify and discuss issues relevant to clinical development of oncolytic viruses including safety. The following viruses will be covered: Adenovirus, herpes simplex virus, reovirus, Newcastle disease virus, measles virus, and Sendai virus. Speakers will address selectivity, attenuation modes, shedding, clinical and viral safety, and proof of concept in support of the approach in animal and human setting.

*Date and Time:* The workshop will be held on November 7, 2005, from 8 a.m. to 5 p.m.

*Location:* The public workshop will be held at the Westin Michigan Avenue, 909 North Michigan Ave., Chicago, IL 60611.

*Contact Person:* Daniel Takefman, Center for Biologics Evaluation and Research (HFM-720), Food and Drug Administration, Rockville, MD 20852, 301-827-5102, e-mail: [daniel.takefman@fda.hhs.gov](mailto:daniel.takefman@fda.hhs.gov).

*Registration:* Registrations are being collected by the Pharmaceutical Research and Manufacturers of America (PhRMA). Send registration information (including name, title, firm name, address, telephone, and fax number) to Liz Cross at PhRMA by FAX: 202-572-7797, or e-mail: [lcross@phrma.org](mailto:lcross@phrma.org), no later than Friday, October 14, 2005. The registration fee for this workshop is \$450 for industry; \$175 for academia and government participants. To register via the Internet go to <http://www.ich.org/cache/html/2238-272-1.html>.

The registration fee will be used to offset some expenses of hosting the workshop including speakers, meeting rooms, coffee breaks, and materials.

If you need special accommodations due to a disability, please contact Liz Cross at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in the European Union (EU), Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

ICH's steering committee recognized that in the rapidly evolving area of gene therapy medicinal products, there is a need to continue to foster the exchange of information that may impact the regulation of such products. The Gene Therapy Discussion Group (GTDG) is leading these activities within ICH.

Regulatory and industry representatives from the three ICH regions (EU, Japan, and the United States), and experts from the European Free Trade Association, Health Canada, and the World Health Organization participate in this group.

The objectives of GTDG are to monitor emerging scientific issues and proactively set out principles that may have a beneficial impact on harmonizing regulation of gene therapy products.

The current ICH process and structure can be found on the Internet at <http://www.ich.org> (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

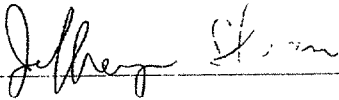
The agenda and registration form for the public workshop are available on the Internet at <http://www.ich.org/cache/html/2238-272-1.html> (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The workshop agenda includes panel discussions in addition to invited presentations. A summary of the workshop will be available through ICH after the meeting.

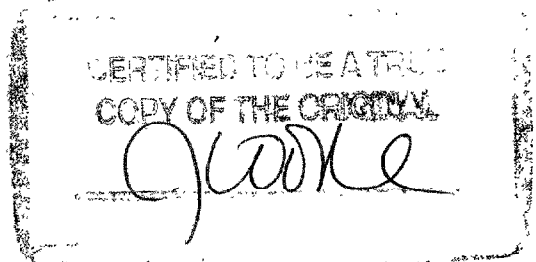
**SEP 20 2005**

Dated: \_\_\_\_\_

September 20, 2005.



Jeffrey Shuren,  
Assistant Commissioner for Policy.



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